

September 4, 2008

Montana Healthcare Programs Notice

Physicians, Mid-Level Practitioners, and Pharmacy Providers

SmartPA[®] Prior Authorization for Synagis[®]

In the United States, respiratory syncytial virus (RSV) infection accounts for more than 90,000 pediatric hospitalizations and 4,500 deaths annually. Symptoms of RSV are usually self-limiting in those individuals that are considered healthy and have normally developed respiratory systems. However, the risk of serious RSV illness is highest among pediatric patients with specific risk factors (i.e., prematurity, chronic lung disease, congenital heart disease, multiple congenital anomalies, and certain immunodeficiencies). Synagis[®] (palivizumab), is a humanized monoclonal antibody (IgG1k) produced by recombinant DNA technology that binds to the F glycoprotein of RSV.

RSV prophylaxis with Synagis[®] for patients with less severe underlying disease is generally not recommended for more than one RSV season and should be reserved for those patients with more severe chronic lung disease (i.e., those requiring medical therapy).

Synagis[®] is dosed at 15 mg/kg every 28 days during the RSV season. While costs of a single 100 mg vial approximates \$1400, total cost for treatment may exceed \$5,000 per patient per season; therefore prior authorization is imperative to promote prudent prescribing of this agent.

Approval Criteria

Beginning October 6, 2008, Montana Medicaid will implement the following SmartPA[®] criteria for Synagis[®]:

- Synagis[®] will be approved during the RSV season from October 1- May 31.
- Treatment is being administered at the start or within the RSV season.
- < 2 years old with chronic lung disease that required treatment in the past 6 months.
- Patients born < 28 weeks of gestation* and are currently < 1 year of age.
- Patients born between 29 and 32 weeks gestation* and are currently < 6 months of age.
- Patients born between 32 and 35 weeks gestation* and are currently < 6 months of age if they have two or more multiple risk factors present such as:
 - Child care attendance
 - School-aged siblings
 - Exposure to environmental air pollutants
 - Congenital abnormalities of the airways

- Severe neuromuscular disease
- Low birth weight
- Long distance from hospital care
- < 24 months of age with hemodynamically significant cyanotic and acyanotic congenital heart disease.
- Infants younger than 24 months of age with congenital heart disease who most likely are to benefit from immunoprophylaxis such as:
 - Those receiving medication to control CHF
 - Those with moderate to severe pulmonary hypertension
 - Those with cyanotic heart disease
- Children with severe immunodeficiencies who may benefit from prophylaxis (subject to clinical/medical review)

*Weeks gestation calculated by completed weeks of gestation.

If the claim denies for prior authorization and the prescriber or pharmacist wants to pursue obtaining a prior authorization, the prescriber or pharmacy may submit requests by mail, telephone, or fax to:

**Drug Prior Authorization Unit
Mountain Pacific Quality Health Foundation
3404 Cooney Drive
Helena, MT 59602
(406) 443-6002 or (800) 395-7961 (phone)
(406) 443-7014 or (800) 294-1350 (fax)**

Any questions regarding this notice can be directed to Wendy Blackwood at (406) 444-2738 or the Medicaid Drug Prior Authorization Unit.

Contact Information

For claims questions or additional information, contact Provider Relations:

**Provider Relations toll-free in- and out-of-state: 1-800-624-3958
Helena: (406) 442-1837
E-mail: MTPRHelpdesk@ACS-inc.com**

Visit the Provider Information website:

<http://www.mtmedicaid.org>